FILED UNDER SEAL

IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA

PLAINTIFFS' UNDER SEAL	:	
	:	
v.	:	CIVIL ACTION NO. 03-CV-3983
	:	**(FILED UNDER SEAL)**
DEFENDANT UNDER SEAL	:	
	:	
Defendant.	:	

THE UNITED STATES' RESPONSE TO
(1) RELATOR'S BRIEF FILED NOVEMBER 16, 2009,
and (2) DEFENDANT'S MOTION TO UNSEAL

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FILED UNDER SEAL

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, ex rel. JOHN UNDERWOOD, PLAINTIFF,	:	
v.	:	CIVIL ACTION NO.03-3983 **FILED UNDER SEAL**
GENENTECH, INC., and ROCHE HOLDINGS, INC. DEFENDANTS.	:	

THE UNITED STATES' RESPONSE TO:
(1) RELATOR JOHN UNDERWOOD'S BRIEF FILED NOVEMBER 16, 2009,
AND
(2) DEFENDANT GENENTECH'S MOTION TO UNSEAL

The Court has asked the government for its views on the question whether the United States has an obligation to release to relator John Underwood the documents produced by Genentech in the government's investigation of relator's allegations in this qui tam action, in light of the arguments asserted by relator and Genentech in their respective submissions made to the Court on November 16, 2009.

I. Status Of Requests By Relator, Government's Response, And Resolution

A. Relator's Requests For Investigative Files And Government's Response

After the government declined to intervene in this action, relator requested that the government share its investigative files with him, before he determined whether to proceed with this action, and before the seal was lifted in this action. Relator made eleven requests for documents, most of which were the documents of third parties obtained by the government in the course of its investigation of relator's allegations. The government declined to share those documents, and among its reasons was a concern that the third parties whose materials were sought be allowed the opportunity to object or assert a position with regard to production of their materials to a relator in a declined qui tam action that is still under seal. The essential issue for the government was notice to those third parties and an opportunity for each of them to assert their own position with regard to sharing their information with the relator in a declined case.

B. Resolution By Relator And The Government

After discussions with government counsel of the government's concerns, relator agreed to serve a subpoena for a narrowed set of just three of his original requests. The three subpoena requests were for: (i) all documents produced by the relator himself to the government in the course of its investigation, (ii) all Medicare claims (in redacted form) relating to the drug at issue, Rituxan, for the time period at issue, and (iii) all documents produced by Genentech to the government in its investigation. A copy of the relator's subpoena is attached.

With regard to relator's own documents, notice and consent from relator were not an issue; the government has produced those materials to relator. With regard to the redacted Medicare claims, the government notified HHS of relator's request and ascertained that the data would be available from the agency through a FOIA request or in third party discovery, and therefore those data have been produced to relator.

With regard to Genentech's documents, government counsel and relator's counsel agreed that the government would notify Genentech of relator's request for the company's documents, and allow the company to assert its position on production of the documents to relator's counsel and the Court.[1] The government agreed with relator's counsel and Genentech's counsel that the government would not share the documents with relator until Genentech's position had been addressed by either the Court or relator. Accordingly, because the United States understood that the issues between relator and the government were resolved, counsel agreed that neither the government nor relator would file briefing on November 16, 2009. This agreement was memorialized in two letters dated November 6, 2009, to the Court and to relator's counsel, respectively. Both are attached. Nevertheless, relator filed a memorandum entitled "Relator John Underwood's Brief Pursuant To This Court's Orders of October 7 And 26, 2009" on November 16, 2009.

C. Government's Obligation At This Point

The government's position remains the same as originally expressed to the Court some weeks ago: the government has no obligation to turn over its investigative files to a relator in a declined qui tam case without observing appropriate procedural safeguards. In this case, the relator agreed to appropriate safeguards: service of a subpoena and notice to non-participants whose documents were sought. Thus, all that remains is for the Court to adjudicate Genentech's request that the government not turn over its company documents to relator until the complaint is unsealed and served upon defendant. Once the company's objections have been addressed by the Court or by relator, the government will produce the documents to relator according to the terms of that resolution, whether it be the Court's order or an agreement between relator and the company.

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[1] In his memorandum, relator states that Genentech "voluntarily" produced the documents to the government. Mem. at pp. 3, 7. More accurately, the Genentech documents were obtained by means of a HIPAA subpoena served upon the company.

The resolution of relator's document requests, including relator's conduct in serving the subpoena and agreeing that Genentech counsel be notified, is consistent with the government's position that it is a non-party after having declined to intervene in this qui tam action. The procedure followed here included notifying third parties and non-parties who may have an interest in protecting the materials sought by the relator, and is essentially the procedure followed when seeking third party discovery via a Rule 45 subpoena. This is the proper procedure for discovery in a declined qui tam case, as described to the Court in the government's letter dated October 6, 2009.

As a result of appropriate safeguards having been effected via the resolution between the government and relator, and upon learning of Genentech's intent to assert a position on production of its documents, all three participants agreed that Genentech would present its position on production of its documents to the Court and allow it to resolve the issues presented. The government stands by that agreement, and therefore is prepared to produce the company's documents to relator once the Court rules on Genentech's motion, or the participants reach alternative terms for dealing with relator's request for Genentech's documents. The procedure followed here is what occurred in U.S. ex rel. Burns v. Family Practice Associates of San Diego, 162 F.R.D. 624 (S.D. Cal. 1995), discussed by relator in his memorandum at pages 7-9. There, as here, the government gave notice of the request to produce the documents, defendant raised objections, and the court ruled on those objections. That is the process the government recommends in this case.

II. Government's Response To Question Addressed By Relator In His November 16, 2009 Memorandum

In his November 16, 2009 submission to the Court, relator elected to respond to one of the questions set forth in the Court's October 7, 2009 order: "Are the non-grand jury materials Relator seeks from the Government available through customary means of discovery? If so, why is relator entitled to the materials provided to the Government?"

The government's response to this question is yes, the materials sought by relator are available through customary means of discovery, and those are the means by which the materials should be obtained. Relator is not entitled to demand that the government violate its duty to respect the established procedures (pursuant to FOIA, Touhy, and similar constraints) that provide notice and an opportunity to be heard to non-participants in the litigation, and produce materials gathered in the course of an investigation without such notice and opportunity. In this case, relator agreed to the government providing such notice, and he agreed that the one participant who raised an issue (Genentech) would be heard before the Court. Thus, the government understood that the issues between the government and relator were resolved.

In his memorandum submission, relator argues that he should be allowed to obtain the company's documents from the government at this stage because the company may not have preserved all the materials and/or may balk at producing them in discovery. Mem. at pp. 2, 5. Relator's argument misses the fundamental point that the materials are available to him *from the government* once the case has been unsealed and third party discovery is served upon the government. Thus, relator's argument that he will be stymied in obtaining the materials is unfounded.

Addressing further the arguments made in relator's memorandum submission, the government disagrees that the relator stands in the shoes of the government in a declined qui tam case such as this one, or is "essentially the same party" as the government (Mem. at p. 6), and disagrees that the relationship between the government and relator in a declined qui tam is such that the government must share its investigative files with relator in the manner relator seeks here.[2] Mem. at p. 8. The government's position and supporting legal authority are set forth at

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[2] Recently, the U.S. Supreme Court held that "when the United States has declined to intervene in a privately initiated FCA [False Claims Act] action, it is not a 'party' to the litigation. United States ex rel. Eisenstein v. City of New York, __ U.S. __, 239 S. Ct. 2230, 2236-2237, 173 L. Ed.2d 1255 (2009). The United States "is a 'party' to a privately filed FCA action only if it intervenes in accordance with the procedures established by federal law." Id. at 239 S.Ct. 2234. A party seeking third-party discovery from the United States must comply with any applicable agency Touhy regulations. See United States ex rel. Touhy v. Ragen, 340 U.S. 462, 468-70 (1951) (upholding regulation prohibiting agency employees from releasing documents without consent of agency head). Consistent with the above, courts have denied motions by relators or defendants to obtain the United States' investigatory files or depose employees of the United States in declined qui tam cases unless those parties comply with all applicable discovery requirements. United States ex rel. Lamers v. City of Green Bay, Wisconsin, 924 F. Supp. 96, 98 (E.D. Wis. 1996); United States ex rel. Drummond v. TRW, Inc., et al., No. 97-0331 (E.D. La. Apr. 3, 1998).

For example, in Drummond, after the United States declined to intervene in a qui tam action and the relator sought to compel the United States to turn over to the relator its investigative file and a written statement describing the contents of that file, the court pointed out that "although the government remains the real party in interest in a qui tam action [it] is not a formal party to this lawsuit. Therefore, [relator] must seek discovery from the United States pursuant to the Federal Rules of Civil Procedure governing nonparties." Drummond, slip op. at 1-2 (citation omitted). The Drummond court went on to explain that neither the False Claims Act nor the Federal Rules of Civil Procedure permit relators to seek materials from "the government, a nonparty," simply by asking the court to compel such an outcome. Id.

United States ex rel. Purcell v. MWI Corp., 209 F.R.D. 21 (D.D.C. 2002), cited by relator, is distinguishable from the situation presented here. First, the government intervened in the Purcell case, unlike this one. Second, in Purcell, *defendant* sought to discover the nature of the relator-government communications, and the government invoked the privilege to shield those communications from the defendant. Purcell, at *22.

In Stalley v. Methodist Healthcare, 517 F.3d 911 (6th Cir. 2008), also cited by relator, the Sixth Circuit distinguished the False Claims Act from the Medicare Secondary Payment Act by noting, among other things, that the procedural safeguards in the FCA exist to allow the greater length in its letter to the Court dated October 6, 2009.[3]

In addition, any argument from relator that he needs the government's investigative files in order to evaluate the case for purposes of deciding whether to proceed to litigate this case after the United States has declined is suspect because relator was obligated to decide whether the case had merit *before* he filed it in federal court. Neither the False Claims Act nor the Federal Rules contemplate a relator filing a speculative complaint and then relying on the government's investigation to determine the merit of the claims. U.S. ex rel. Joshi v. St. Luke's Hosp., Inc., 441 F.3d 552, 559-60 (8th Cir. 2006); United States ex rel. Zelis v. Ritchie, No. 92-5153, slip op. at 2-4 (E.D. Cal. 1992) (after government declined to intervene, it treated relator's request for its files as a FOIA request, and argued that it was not a party, and there had been no subpoena, discovery request or other process to obtain the documents; the court refused to order production, stating "An order interpreting the [False Claims Act] as authorizing automatic access to the contents of government files as suggested by Zelis's attorney would open these files to qui tam plaintiffs regardless of whether the action had merit and would encourage the filing of qui tam

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government to determine the extent to which it would participate in an FCA case. The issue in U.S. ex rel. Kreindler & Kreindler v. United Technologies Corp., 985 F.2d 1148 (2d Cir. 1993) was the constitutionality of the FCA statutory grant of standing to a relator to bring an FCA action. In U.S. v. Menominee Tribal Enterprises, 601 F. Supp.2d 1061 (E.D. Wis. 2009), the issue was whether an Indian tribe was a "person" who could be sued under the FCA. None of these analyses is apt to the issue presented here, and the general language quoted by relator does not support his argument that he is entitled to the United States' investigative files in a declined and still sealed qui tam action without observing procedural safeguards.

[3] Relator also argues that Genentech has waived any privilege or work product protection that it might invoke as to its documents produced to the government. Mem. at pp. 7-9. The government does not address those arguments as they are directed to Genentech, and moreover, as explained above, the government's concern for notice and opportunity to be heard has been addressed as to Genentech in this case.

actions for the principal purpose of obtaining access to government files.").

As a matter of common sense as well as law, it is inaccurate to say that relator and the government have the same interests in this case. The government has determined that its interest lies in declining to intervene in the relator's case and declining to pursue relator's claims. Relator's interest at this point is in a potential monetary recovery for himself – albeit shared with the government. Relator cannot hijack the government to be his co-plaintiff. United States by Dep't of Def. & Pentagon Techs. Int'l, Ltd. v. CACI Int'l, 953 F. Supp. 74 (S.D.N.Y. 1995) ("While a qui tam relator is empowered as a private prosecutor, it is not empowered to replace the government. There is nothing in the FCA which gives the relator power over the conduct of government officials.").

III. Government's Response To Genentech's Motion To Unseal The Complaint

The government does not object to the Court's ordering that the seal be lifted as to the complaint in this action, as requested by Genentech, so that relator and defendant can move forward with the litigation. In the typical qui tam case, when the government files its notice of declination, it requests that the complaint be unsealed. Out of deference to the relator's counsel's request, the government did not affirmatively seek to have the seal lifted on September 25, 2009, when it filed its notice of declination, and instead acquiesced to the seal expiring on the date previously set by the Court's order. Subsequently, relator sought and obtained an order that the seal continue until December 31, 2009. Again, the government did not object.

The government has no objection to the Court's lifting the seal on the complaint in this case and ordering the relator and Genentech to proceed to litigation. Indeed, doing so would obviate any further document production issues because relator would then be able to seek discovery through the normal means from parties to the action as well as non-parties, including the government, and both litigants and non-litigants would have the opportunity to be heard on discovery sought from them. The purpose of the seal – to protect the government's investigation of the qui tam allegations – is eliminated, as the government has concluded its investigation and already filed its notice of declination. Relator himself, in his November 16 memorandum submission, asserts that he is litigating this action (Mem. at p. 2), and does not interpose an objection to Genentech's request that the Court lift the seal. It appears that all interested participants – the government, the relator, and the defendant – would be best served by a lifting of the seal in this matter.

IV. CONCLUSION

Based upon the foregoing, the United States has no objection to the Court ordering that the seal be lifted as to the complaint and any amended complaints in this action so that relator and defendant may pursue discovery pursuant to the Federal Rules of Civil Procedure, and requests that the Court rule on Genentech's request for a protective order regarding its documents.

Dated: November 20, 2009

Respectfully submitted,

MICHAEL L. LEVY
United States Attorney

MARGARET L. HUTCHINSON
Chief, Civil Division
Assistant United States Attorney

VIVECA D. PARKER
Assistant United States Attorney

AO 88B (Rev. 06/09) Subpoena to Produce Documents, Information, or Objects or to Permit Inspection of Premises in a Civil Action

UNITED STATES DISTRICT COURT

for the

Eastern District of Pennsylvania

United States ex rel. John Underwood
Plaintiff
v.
Genentech, Inc. and Roche Holdings, Inc.
Defendant

Civil Action No. 03-3983

(If the action is pending in another district, state where:)

SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION, OR OBJECTS OR TO PERMIT INSPECTION OF PREMISES IN A CIVIL ACTION

To: United States Attorneys' Office - Eastern District of Pennsylvania (Attn: Viveca Parker, Esquire)
615 Chestnut Street, Suite 1250, Philadelphia, PA 19106

☑ *Production:* **YOU ARE COMMANDED** to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and permit their inspection, copying, testing, or sampling of the material: See attached Schedule A.

Place: Schnader Harrison Segal & Lewis LLP 1600 Market Street, Suite 3600, Philadelphia, PA 19103	Date and Time: 11/10/2009 4:30 pm

☐ *Inspection of Premises:* **YOU ARE COMMANDED** to permit entry onto the designated premises, land, or other property possessed or controlled by you at the time, date, and location set forth below, so that the requesting party may inspect, measure, survey, photograph, test, or sample the property or any designated object or operation on it.

Place:	Date and Time:

The provisions of Fed. R. Civ. P. 45(c), relating to your protection as a person subject to a subpoena, and Rule 45 (d) and (e), relating to your duty to respond to this subpoena and the potential consequences of not doing so, are attached.

Date: 11/03/2009

CLERK OF COURT

____
Signature of Clerk or Deputy Clerk

OR

[signature]
Attorney's signature

The name, address, e-mail, and telephone number of the attorney representing *(name of party)* John Underwood , who issues or requests this subpoena, are:

H. Justin Park, Schnader Harrison Segal & Lewis LLP, 1600 Market Street, Suite 3600, Philadelphia, PA 19103, jpark@schnader.com, (215) 751-2000

Federal Rule of Civil Procedure 45 (c), (d), and (e) (Effective 12/1/07)

(c) Protecting a Person Subject to a Subpoena.

(1) *Avoiding Undue Burden or Expense; Sanctions.* A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The issuing court must enforce this duty and impose an appropriate sanction — which may include lost earnings and reasonable attorney's fees — on a party or attorney who fails to comply.

(2) *Command to Produce Materials or Permit Inspection.*

(A) *Appearance Not Required.* A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises — or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

(i) At any time, on notice to the commanded person, the serving party may move the issuing court for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) *Quashing or Modifying a Subpoena.*

(A) *When Required.* On timely motion, the issuing court must quash or modify a subpoena that:

(i) fails to allow a reasonable time to comply;

(ii) requires a person who is neither a party nor a party's officer to travel more than 100 miles from where that person resides, is employed, or regularly transacts business in person — except that, subject to Rule 45(c)(3)(B)(iii), the person may be commanded to attend a trial by traveling from any such place within the state where the trial is held;

(iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or

(iv) subjects a person to undue burden.

(B) *When Permitted.* To protect a person subject to or affected by a subpoena, the issuing court may, on motion, quash or modify the subpoena if it requires:

(i) disclosing a trade secret or other confidential research, development, or commercial information;

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party; or

(iii) a person who is neither a party nor a party's officer to incur substantial expense to travel more than 100 miles to attend trial.

(C) *Specifying Conditions as an Alternative.* In the circumstances described in Rule 45(c)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

(i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and

(ii) ensures that the subpoenaed person will be reasonably compensated.

(d) Duties in Responding to a Subpoena.

(1) *Producing Documents or Electronically Stored Information.* These procedures apply to producing documents or electronically stored information:

(A) *Documents.* A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) *Form for Producing Electronically Stored Information Not Specified.* If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(C) *Electronically Stored Information Produced in Only One Form.* The person responding need not produce the same electronically stored information in more than one form.

(D) *Inaccessible Electronically Stored Information.* The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) *Claiming Privilege or Protection.*

(A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

(i) expressly make the claim; and

(ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

(B) *Information Produced.* If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information to the court under seal for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(e) Contempt. The issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena. A nonparty's failure to obey must be excused if the subpoena purports to require the nonparty to attend or produce at a place outside the limits of Rule 45(c)(3)(A)(ii).

SCHEDULE A

Definitions

1. "Document" is intended to be given the broadest possible scope and includes any written, recorded or graphic matter, or any other means of preserving thought or expression, including all non-identical copies, drafts, worksheets, work papers, proofs, whether handwritten, typed, printed, photocopied, photographed, tape-recorded, transcribed, filed or otherwise created, specifically including, but not limited to, telephone slips and logs, diary entries, facsimiles, presentations, calendars, reports, spreadsheets, minutes, correspondence, memoranda, notes, videotapes, audio tapes, electronic or digital recordings of any kind, photographs, and any other form of communication or representation. It also includes, without limitation, all information stored in a computer system although not yet printed out, all information stored on computer hard drives, all information stored on floppy diskettes, computer tape backups, CD-ROM, and/or e-mail.

2. "Communication" means any transmission of thoughts, opinions, data, or information, in the form of facts, ideas, inquiries, or otherwise, including, without limitation, correspondence, letters, e-mail, facsimiles, reports, memoranda, contacts, discussions, calculations, presentations, and any other written or oral exchanges between any two or more persons.

3. "Correspondence" should be construed in its broadest possible sense. It includes, but is not limited to, letters, e-mails, faxes, oral communications, and any other communications and the documents contained in those communications.

4. "Genentech" means Genentech, Inc., its employees, officers, directors, shareholders, agents, representatives, attorneys, advisors, partners, affiliates, subsidiaries, assigns, and anyone else acting under its control or on its behalf.

5. All words and phrases shall be construed in accordance with normal custom and usage in the industries or field of commerce to which they apply.

6. "Relating to" should be construed in the broadest possible sense to include approving, concerning, constituting, describing, discussing, evidencing, memorializing, mentioning, pertaining to, questioning, referring to, regarding, relying on, reviewing, showing, about, relating in any way to, related to, tending to prove, or tending to disprove.

7. "Or" and "and" shall be construed either conjunctively or disjunctively to bring within the scope of the below document requests any information that might otherwise be construed to be outside their scope. The past tense includes the present tense where the clear meaning is not distorted by change of tense.

8. The use of the singular form of any word includes the plural and vice versa.

9. "The Government," "you," and "your" refer to the federal government of the United States, including the Office of the United States Attorney for the Eastern District of Pennsylvania and its employees, agents, representatives, and attorneys.

10. "Participated in" should be construed in the broadest possible sense to include participating, offering advice, offering criticism, offering insight, making suggestions, making decisions, and editing.

11. "This action" refers to the civil action pending in the United States District Court for the Eastern District of Pennsylvania and captioned: *United States ex rel. Underwood v. Genentech, Inc.*, No. 03-3983 (E.D. Pa.).

Documents Requested

1. Any and all documents produced to you by Genentech, which pertain to the Government's civil or criminal investigations of Genentech triggered by the allegations raised in this action, excluding any produced exclusively in response to a grand jury subpoena.

2. Any and all documents produced to you by the Centers for Medicare and Medicaid Services, which pertain to the Government's civil or criminal investigations of Genentech triggered by the allegations raised in this action, except for any produced exclusively in response to a grand jury subpoena.

3. Any and all documents provided to you by Relator John Underwood.

U.S. Department of Justice

United States Attorney

Eastern District of Pennsylvania

Viveca D. Parker
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November 6, 2009

Honorable Paul S. Diamond
Judge, United States District Court
6613 United States Courthouse
601 Market Street
Philadelphia, PA 19106-1744

VIA HARD COPY AND FACSIMILE
TO (267) 299-5069

Re: United States ex rel. Underwood v. Genentech, Inc., Civ. No. 03-3983
UNDER SEAL

Dear Judge Diamond:

This will update Your Honor on the status of the relator's request for certain documents obtained in the Government's investigation of the allegations made in the above referenced qui tam action. The Government and the relator have resolved the issues raised with regard to sharing of the documents. As part of that resolution and pursuant to agreement with relator's counsel, the Government notified counsel for Genentech that relator sought the company's documents produced to the Government in its investigation, and the company requested that the documents not be shared until it had the opportunity to be heard before Your Honor. Therefore, all that remains to be resolved with respect to discovery before the service of the complaint on Genentech is briefing by Genentech and the relator on their respective positions regarding access to the company's documents on November 16, 2009.

Very truly yours,

MICHAEL L. LEVY
United States Attorney

Viveca D. Parker

cc Elizabeth Ainslie, Esquire

U.S. Department of Justice

United States Attorney

Eastern District of Pennsylvania

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(215) 861-8200

November 6, 2009

Elizabeth Ainslie, Esquire
Schnader Harrison Segal & Lewis LLP
1600 Market Street, Suite 3600
Philadelphia, PA 19103-7286

RE: U.S. ex rel. Underwood v. Genentech, Inc., Civ. No. 03-3983 UNDER SEAL

Dear Ms. Ainslie:

As a result of our discussions over the last weeks, enclosed with this letter please find the following documents requested in your November 3, 2009 subpoena:

1. Redacted Medicare claims data received from the Centers for Medicare and Medicaid Services pertaining to Rituxan during the time period relevant to this action; and

2. All documents produced to the Government by Relator John Underwood.

Please note that, as we agreed with you, we are not producing any documents received from Genentech in the course of the Government's civil and criminal investigations related to this action. As I explained in my October 26, 2009 letter to you, Genentech disputes our producing these documents and intends to assert its position either directly to you or before the Court by the November 16, 2009 briefing deadline. We will await a resolution of this dispute between you and Genentech before making any production of this category of documents.

Finally, as we have agreed, your service of a narrowed subpoena and this production obviates the need for us to brief issues before the Court. We will undertake to inform the Court that the issues raised between us have been resolved, and that the Court should expect only briefing by Genentech on its position regarding its own documents. All that is left to be resolved with respect to discovery before the service of the complaint on Genentech is briefing by Genentech and the relator about relator's access to company documents.

Thank you for your continued cooperation.

Very truly yours,

MICHAEL L. LEVY
United States Attorney

Viveca D. Parker

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing THE UNITED STATES' RESPONSE TO:

(1) RELATOR JOHN UNDERWOOD'S BRIEF FILED NOVEMBER 16, 2009, AND

(2) DEFENDANT GENENTECH'S MOTION TO UNSEAL was sent by First Class United States Mail, postage prepaid, this 20th day of November, 2009, to the following:

Robert E. Welsh, Jr., Esquire
Welsh & Recker P.C.
2000 Market Street, suite 2903
Philadelphia, PA 19103

Elizabeth K. Ainslie, Esq.
Schnader, Harrison, Segal & Lewis
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Viveca D. Parker